K040876

APR 1 9 2004

6.0 510(k) Summary

Submitter's Name / Contact Person

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Vital Images, Inc.
3300 Fernbrook Lane N, Suite 200
Plymouth, MN 55447

General Information

Trade Name	iConnection, Version 3.2.0.0 Medical Image Processing Software
Common / Usual Name	System, Image Processing, Radiological
Classification Name	LLZ, Class II, CFR 21 892.2050
Predicate Devices	Vitrea 2, Version 3.4 (K032748) Vital Images, Inc. iConnection (K012779) HInnovation, Inc.

Device Description

iConnection provides an online enterprise solution for secure access and on-demand distribution of diagnostic images, reports, clinical applications and services. The iConnection system offers fully integrated diagnostic reviewing, volumetric processing, and collaborative functionalities in a clinically familiar ubiquitous diagnostic environment. It enables its users, primarily radiologists, cardiologists, and referring physicians, to streamline clinical workflow and access, review, and visualize patient data with high-end applications.

The iConnection system has an applications server which provides centralized data management and application processing and a thin-client web-based viewer.

An iConnection system consists of the follow components: 1) a server; 2) one or more client computers (referred to as client); and 3) the Client/Server communication.

Intended Use

iConnection™ 3D[1] is a medical diagnostic software system intended to process, analyze, review, and distribute multi-dimensional digital images acquired from a variety of imaging devices including: CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc. In addition, the iConnection system has the following specific intended uses:

Advanced Vessel Analysis is an option within the iConnection system intended to aid clinicians in the study and analysis of selected vessels, the inspection of circulatory anatomy, the quantification of stenosis, distance measurements and cross-sectional diameters, volume measurements, and assist in the planning and monitoring of vascular therapies. The feature operates with CT and MRI data.

Pet Visualization is an option within the iConnection system that provides for the overlay, inspection, and measurement of two different image modalities (primarily directed at PET/CT). The option also includes the ability to measure Standard Uptake Values on PET datasets.

The overlay operation enables clinicians to obtain a better understanding of the joint information that would otherwise have to be compared separately. It is important to note that the clinician retains the ultimate responsibility for making pertinent diagnosis based on their standard procedures, including visual comparison of separate images.

Collaboration Mode is a capability within the iConnection system that allows multiple users to collaboratively interact with iConnection system features and tools.

[1] The final product name has not yet been determined. The iConnection system refers to the HInnovation, Inc. product from which the capabilities are derived.

Predicate Device Comparison

The iConnection system and its predicate devices allow for the analysis, communication and media interchange of digital images acquired from a variety of acquisition devices. All devices support the DICOM protocol for communication of images with other medical imaging devices.

Summary of Studies

The software utilized was designed, developed, tested, and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating and maintenance.

The iConnection system will successfully complete integration testing/verification testing prior to Beta validation. Software Beta testing/validation will be successfully completed prior to release. In addition, potential hazards have been studied and controlled by a Risk Management Plan.

Conclusion

The iConnection system has very similar intended uses and very similar technological characteristics as compared to the predicate devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, the iConnection system is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 9 2004

Vital Images, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K040876
Trade/Device Name: iConnection, Version 3.2.0.0 Medical Image Processing Software
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 31, 2004
Received: April 5, 2004

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3.0 Intended Use Statement

510(k) Number (if known): K040876

Device Name: iConnection™ 3D Medical Image Processing Software

iConnection 3D[1] is a medical diagnostic software system intended to process, analyze, review, and distribute multi-dimensional digital images acquired from a variety of imaging devices including: CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc. In addition, the iConnection system has the following specific intended uses:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

Prescription Use √

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040876